TAB H

OPTION PAPER ON AWP REFORM

Issue

What position or positions should J&J take on reforming the AWP payment system?

Background

The current reimbursement method for Medicare Part B drugs/biologics has created incentives for physicians to purchase drugs/biologics with the largest "spread" between the cost of the products and what the government reimburses, using published average wholesale price or AWP. Both the General Accounting Office and the HHS Inspector General have called for legislative changes in the methodology because the current AWP method overpays physicians for the cost of covered drugs. Congress has signaled its interest in changing the methodology this year – both the House Energy and Commerce and the House Ways and Means committees have developed proposals to move away from AWP.

J&J is interested in a change in methodology, because we agree that the methodology creates inappropriate incentives and competitors are taking advantage of the "spread" to appeal to our customers. In addition to potential changes in the AWP methodology, we also face serious challenges this coming year in the outpatient hospital PPS payment system. PROCRIT™, among a large number of drugs/biologics and medical devices, loses its status as a cost passthrough while ARANESP™, our chief competitor product, will generate for hospitals favorable passthrough reimbursement for two more years.

This issue is very sensitive with our customers, who have made the case that the "overpayment" in Medicare reimbursement compensates them for unrecognized practice, inventory, and other costs. So while we would like to see a change as soon as possible, it must be a change that will adequately cover physicians' costs.

Legislative objectives

- As part of any AWP reform, there must be adequate physician compensation to reimburse for the cost of administering drugs/biologics. This is essential for our customers. We believe we have developed a viable proposal.

- Encourage AWP reform that would not create burdensome reporting requirements or incentives for "gaming."
- The effective date for an AWP change should be as soon as possible, either January 1, 2003 or January 1, 2004, in order to minimize the time when we are subject to an "unlevel playing field."
- The new methodology should apply to the outpatient hospital setting as well as the physician's office. In this regard, we differ from our competitors and many of our customers. PhRMA is also likely to be opposed.
- Oppose any competitive bidding approach to purchasing Part B drugs that would result in an even greater concentration of purchasing power with PBMs. We would like a broader array of suppliers, for example, groups like McKesson and SureScripts.

Current proposals

- ***ASP Method*** – This approach was considered last year by the House Energy and Commerce Committee. It would base payment for the drug on average selling price. Last year, Congressional staff talked about setting payment at ASP+20%. Earlier this year, we heard ASP+8%. We understand that the committee staff are working on a proposal, but we do not know the % add on. This approach would require CMS to collect data on the average selling price for drugs reflecting rebates, discounts, etc., something the agency has not done before.
- ***Competitive bidding method*** – This approach was originally part of the Ways and Means Committee Medicare bill. It would have PBMs and GPOs bid to supply Part B drugs to physicians. CMS would reimburse physicians at the median of the bids for each covered drug/biologic. The physician would purchase the drug/biologic from the supplier who could provide the best price or prices for the drugs/biologics used by the physician. This approach would require CMS to establish a different function than now exists.
- ***CMS Method*** – This approach would rely on CMS to take regulatory action to change the definition of AWP and to increase physicians' payments. Both the drug payment methodology and the extent of physicians' payments would be at the agency's discretion. Tom Scully, CMS Administrator, has stated that CMS will act to change AWP if Congress does not.

Either of the two House proposals would need to include a physician component to compensate for large reductions in reimbursement for covered drugs. Currently, they have two flaws: 1) they would defer to CMS to decide on an appropriate add-on for physicians' payments; and 2) they focus only on chemotherapy administration and would not add payments for infusion treatment.

Either of the two legislative approaches would take until January 2004 to implement. Not currently on the table is a method that relies on AMP or WAC. If we believe that approach is less burdensome and not subject to the "gaming" that has characterized the AWP methodology, we could advocate it. Also not on the table is AWP-15% or 20%, which could be implemented in 2003.

The American Society of Clinical Oncology (ASCO) is working with Senator Bob Graham to introduce a bill that would replace AWP-5% with ASP+20% and direct the Secretary of HHS to revise the Medicare fee schedule. The revisions would add values for "drug administration services," including chemotherapy administration, therapeutic and diagnostic infusions and injections and values for chemotherapy support services, for example, social worker services, nutrition counseling, and similar services. Both REMICADE™ and PROCRIT™ physician customers would be overpaid relative to current reimbursement. The proposal will cost more than current law, since ASP+20% is very close to current levels of drug reimbursement.

Data analysis and survey work

The Policy Group has been working with consultants to assess how much Medicare reimbursement is associated with payments for covered chemotherapy supportive care drugs and infusion therapy drugs. Consultants have also helped structure add-on payments for physician management services and infusion therapy, that could compensate for reductions in payments for the drugs (see attachment). John Hoffman of Centocor has commissioned a survey of rheumatologists' offices to assess costs associated with REMICADE™ infusion therapy. That survey does a good job of justifying payments of $171 or $109 more than physicians are currently receiving to provide infusion therapy. (It is important to note that the $171 only covers the direct out-of-pocket costs. It does not include other real costs such as carrying cost, bad debt expense, etc. which add-on an

additional $25 of costs. As a result, unless the payment is at least $195-$200, there is a real risk that many physicians will stop infusing patients)

Options for Increasing Physician Payments

We have tried to go beyond the non-specific language in current legislative proposals, by developing specific dollar add-ons to physicians' fees that can be legislated, then later be folded into the Medicare fee schedule. We focused on two ways to compensate physicians as part of an AWP reform law change:

- Physician management fee, which would pay physicians for costs now being covered through payments for drugs. This fee would be provided weekly for chemotherapy/supportive care drugs and per infusion for infusion therapy.
- Infusion therapy practice expense increases, which would add dollars to what physicians get paid for performing infusion therapy. This increase would benefit both oncologists and rheumatologists.

Option 1—Management fee only
$100 per week oncology and supportive care management fee; $100 per infusion therapy management fee. (based on the equivalent reduction in drug payment to AWP-15%) (This will need to be higher if the infusion fee payment stays at $62. The total payment will have to be approximately $200 – see my explanation above)

Option 2 – Management fee, with increased payments for infusion therapy
$50 per week for oncology and supportive care management; $50 per infusion for infusion management; and $75 per hour for uncovered costs of infusion therapy services. (based on the equivalent reduction in drug payment to AWP-15%) (This is good. The total payment for a 2-hour infusion would be $200- in line with the actual costs incurred)

These add on payments can be justified using the Centocor survey and information about oncologists' practice costs. Ortho Biotech and Centocor strongly prefer Option 1, a management fee only, because a simpler approach would be easier to advocate. (I don't agree from a Centocor perspective – see above) Option 1 would produce savings, largely from infusion therapy. However, the Judith Baker study justifies an add on of $100. Oncologists would likely be eligible for only one of the two $100 fees

on weeks where they are also providing infusion therapy. The AMA has recommended, and CMS may implement for 2003, added practice expense payments for infusion therapy, which could increase the overall amounts these physicians will receive. (It is not clear to me what we are saying here)

Option for application to the outpatient hospital setting

Option – Application of AWP change to the OPD
We want any change in AWP to apply to the hospital outpatient department. This helps with the "level playing field" problem that arises because PROCRIT™ loses its passthrough status.

No disagreement from Ortho Biotech or Centocor on this option. However, ASCO and ACCC are not likely to support this position.

Option for Effective Date

Option 1 – January 2003
An effective date of January 2003 would help us immediately in payment parity, both in physicians' offices and potentially hospital outpatient departments under the APC system. However, because a change ot ASP or competitive bidding is operationally challenging for CMS, the only change that would permit a 2003 effective date would be if Congress were to enact a two-stage change, with AWP-15% or 20% going into effect in 2003 and ASP or competitive bidding in 2004. If Congress leaves implementation to CMS, it's theoretically possible to implement a change effective January 2003, but CMS does not have the time to issue necessary regulations that quickly. (Unless this is a huge issue for OBI, Centocor would prefer a 2004 implementation date)

Option 2 – January 2004
Legislative proposals set an effective date of January 2004. Most of our customers are expecting and would accept a January 2004 date. Both Centocor and Ortho Biotech support this option.

Next steps

- Decide how proactive we want to be in advocating a position on AWP reform, particularly a specific dollar add on in law for physicians.

- Meet with partners (ASCO, ACCC, ACR, ACG) and stakeholders to try to get buy-in and support for our position, recognizing that they are not likely to support extension of AWP reform to hospital outpatient payments.
- If proactive, work with the Senate and the House Energy and Commerce Committee staff to advocate our position.
- Meet with Tom Scully to share our data and analysis, in the event Congress decides to leave AWP reform to the agency.

Attachment

(The following analysis was done to develop add on payments through a management fee and infusion therapy payments. However, we can combine the payments so that the whole payment is made through a management fee.)

Our analysis shows that we need to come up with a physician management fee that can either be a weekly management fee or a per infusion fee. Based on an analysis of the frequency of claims and total Medicare payments in 1999 and 2000, we propose a weekly chemotherapy management fee of $100-$150 for oncologists that would overcome the losses in total payments associated with a decrease in payments for drugs/biologics to AWP-15% or AWP-20%, respectively. For rheumatologists and gastroenterologists, our proposal focuses on two distinct components of infusion therapy. First, we propose an infusion management fee of $50.

Second, we considered a revision of the current payment amounts for infusion therapy. An extensive study of infusion therapy costs in physicians' offices by Judith Baker, PhD, CPA of the Resource Group, Ltd. demonstrates that the actual costs of a two hour infusion are $171. An increase in payment for a two hour infusion to $171 would result in $109 in additional payment for the service above the current amount of $62. The combination of an infusion management fee and an increase in payments for the infusions themselves would result in increased physician payments of $159 per infusion for reheumatologists and gastroenterologists. This would overcome 83% or 55% of the losses in total payments associated with a decrease in payment for drugs/biologics to AWP-15% or AWP-20% respectively. Details regarding our method of determining the appropriate additional payment amounts follow.

To determine an appropriate level of reimbursement, we first analyzed the frequency of claims and total Medicare payments in 1999 and 2000 to oncologists, rheumatologists and gastroenterologists. The key findings were:

- Oncologists: Drug/biologic payments to oncologists totaled $1.6 billion in 1999 and $2.1 billion in 2000. Of this amount, PROCRIT™ accounted for $318 million in 1999 and $455 million in 2000. Drug/biologic payments account for a significant percentage of total Medicare payments

to oncologists. In total, drugs accounted for a slightly higher fraction of Medicare revenues in 2000 (68%) than they did in 1999 (66%). Although the 2000 distribution of spending is not very different from 1999, the total dollars and the estimated dollars per physician grew substantially. In 2000, there was about $250,000 per physician in Medicare allowed charges for drugs, versus about $200,000 per physician in 1999.

- Rheumatologists: Drug/biologic payments to rheumatologists totaled $15 million in 1999 and $60 million in 2000. In 1999, drugs were about 5% of their allowed charges. In 2000, that rose to 16% of their allowed charges, due solely to REMICADE™. REMICADE™ (infliximab) had a significant impact on rheumatologists' Medicare allowed charges. REMICADE™ accounted for 11% of rheumatologists' 2000 Medicare allowed charges, or about $13,000 per physician in 2000.
- Gastroenterologists: Drugs do not matter much for determining gastroenterologists' Medicare allowed charges. REMICADE™ had essentially no impact on gasterenterologists' revenues. In 2000, it accounted for about $200 per physician in allowed charges, or about 0.15% of total allowed charges.

We next determined the total decrease in payments to oncologists and rheumatologists that would occur if current drug payments were reduced for AWP-5% to AWP-15% or AWP-20%. The results are included in the following table:

Specialty	Loss at AWP-15%	Loss@ AWP-20%
Oncology	$169,703,877	$254,555,816
Rheumatology	$6,276,698	$9,415,047

To determine the amount of a chemotherapy/infusion fee that would be necessary to overcome these potential losses, we used the utilization data to develop estimates of the numbers of infusions provided each year by each specialty. For oncology, we estimated 1.7 million infusions/year and for rheumatology we estimated 33 thousand infusions/year. By dividing the potential losses by these estimated numbers of infusions, we were able to estimate the following amounts of additional payments per infusion that would be necessary for each specialty under the two potential AWP reductions. The results are included in the following table:

Specialty	Additional payments necessary to overcome losses at AWP-15%	Additional payments necessary to overcome losses at AWP-20%
Oncology	$100	$150
Rheumatology	$190	$285

For oncologists, we considered a weekly chemotherapy management fee of $100 to cover the variety of services typically provided to cancer patients by oncologists and their

professional staffs for which there is no explicit reimbursement. Payment for these services would be limited to those weeks during which chemotherapy and/or supportive care were provided. These services include extensive support that seriously ill cancer patients frequently require, including

- Physician work outside the patient's presence, including family counseling, telephone calls and arranging for entry into clinical trials.
- Social worker services necessary to help patients carry out their therapy, such as help with insurance, arranging transportation to treatment, and filling prescriptions.
- Psychosocial support including counseling patients on their activities of daily living, support groups that meet in the physician's office, and grief counseling.
- Nutrition counseling.

For rheumatologists, we focused on two distinct components of infusion therapy. Combined, these two components would result in increased physician payments of $159 per infusion.

First, we considered an infusion management fee of $50 to cover the variety of services typically provided to arthritis patients by rheumatologists and their professional staffs for which there is no explicit reimbursement. Payment for these services would be limited to those occasions when an infusion was provided. These services are similar but less intensive than those provided by oncologists, resulting in a proposal for a lower payment amount.

Second, we considered a revision of the current payment amounts assigned to the two CPT codes (90780 and 90781) used to report infusion therapy of two or more hours duration. The current payment for a two hour infusion is approximately $62. This payment is related to historic charges for the service; it is not based on the resources required to provide it. An extensive study of infusion therapy costs in physicians' offices by Judith Baker, PhD, CPA of the Resource Group, Ltd. demonstrates that the actual costs of a two hour infusion are $171. An increase in payment for a two hour infusion to $171 would result in $109 in additional payment for the service above the current